REMARKS/ARGUMENTS

By the foregoing amendment, claims 12-23 have been cancelled, claims 1 and 7 have been amended and claims 24-26 have been added.

The rejection of claims 1-4, 8, and 10 as anticipated by Borges U.S. patent No. 3,604,414 is respectfully traversed. The present invention provides apparatus for postoperatively dynamically and unidirectionally compressing a bone graft between adjacent vertebrae. The spinal fixation device includes first and second plates each having a pair of generally laterally aligned openings through which fasteners may secure the plates to the respective vertebrae on opposite sides of the graft. Interlocking elements e.g. ratchet teeth, on the first and second plates cooperate with one another to enable progressive postoperative advancement of the plates toward one another and to lock the plates to one another in a plurality of advanced positions precluding movement of the plates away from one another in each advanced position. This permits progressive compression of the bone graft postoperatively. One of the plates also includes a cantilevered leg mounting one of the first and second sets of interlocking elements for flexing movement toward the other set of interlocking elements to enable the progressive advancement and locking of the plates to one another.

Borges does not disclose a device for compressing a bone graft between adjacent vertebrae of the spine nor does it provide for postoperative compression. While the Examiner correctly identifies the two plates and the ratchet teeth in Borges, Borges cannot be utilized for compressing a bone graft between adjacent vertebrae of the spine. The openings 22 in plate 14 as well as the openings 38 in plate 16 are longitudinally aligned with one another. Due to the nature of vertebrae in the spine, screw hole openings longitudinally aligned with one another cannot be utilized in light of insufficient bone structure of the vertebrae for attachment of the Borges device to the vertebrae. .The Borges arrangement is strictly for fixing broken long bones of the limbs, since the

cortical cylindrical bones of the limbs are strong and application of the screws through the opposite walls of the cylinder will give a rigid fixation. Additionally the long bones have lengths sufficient to allow insertion of multiple screws to permit weight bearing on the limb. In contrast the present device has screws laterally arranged to allow adequate fixation in the short spongy bone of the vertebrae.

Secondly, plates 14 and 16 of Borges cannot move relative to one another once the plates are screw fastened to the fractured bone. In Borges, an ancillary tool is used to displace the plates toward one another to draw the fractured bone parts toward one another. In displacing the plates toward one another, the teeth ratchet past one another until the plates are in final disposition. At that time, the surgeon fastens the plates to the bone parts and to one another. The tool is then removed. Once the plates are fixed to one another and to the bone parts, however, the ratchet teeth serve no useful purpose. Postoperatively, the two part Borges device may just as well comprise a single unitary piece spanning the fractured bone parts since they are immobile relative to one another. Moreover, a surgeon would not apply the compression clamp of the Borges system at a surgical site in the neck for fear of injuring vital structures such as the gullet, the wind pipe, the major vessels to the brain and the spinal cord itself. In short, the Borges device is not applicable to the spine.

Further, claim 1 requires a cantilevered leg on one of the first and second plates and which leg is flexible for movement toward and away from the other set of interlocking elements. There is no flexible part in the Borges device since the plates are secured one to the other and to the bones by screws. In other words, Borges the ratchet teeth cannot disengage once final securement and compression has occurred at the time of the operation and therefore the Borges ratchet teeth do not enable progressive advancement of the plates toward one another and do not enable that movement postoperatively.

That is, the ratchet mechanism of Borges device is inflexible and is used by applying the corresponding teeth in the two plates facing each other. Once the

compression has been applied, the system becomes static by virtue of applying locking screws across the two plates into the fractured bone fragment while at the same time securing the plates to one another. The male member of the present ratchet mechanism (claims 5 and 24) has a slit which creates two tooth bearing legs which are deflected under the physiologic weight of the head as the male member advances into the female member, thereby compressing the graft. The slit, the leg or legs and the interlocking elements provide postoperative dynamic compression which continues long after the surgery until a maximum physiologic compressive force has been applied to the graft. From that point, the device converts itself to a static stabilizer.

The rejection of claims 1 and 8 as anticipated by Ralph is respectfully traversed. Ralph discloses a static device which does not enable progressive postoperative advancement of the plates toward one another or locking of the plates to one another in a plurality of advanced positions. While the Ralph Device is designed for spinal fixation, it allows only intraoperative compression and is static post-operatively. The philosophy of physiologic compression force of the weight of the head and spinal motion postoperatively does not play a role in the performance of the Ralph device and is directly opposite to the design of the present invention. Particularly, in Ralph, the legs of the male member 100a may be expanded laterally by locating a set screw through the central opening to lock the male plate to the female plate in an adjusted length position. The advantage set forth in Ralph is that the length of the device can be intraoperatively adjusted. Once the length of the Ralph devices is set, the Ralph device may just as well consist of a single unitary plate rather than two plates since they are incapable of postoperative movement relative to one another.

The rejection of claim 11 as unpatentable over Borges in view of U.S. patent No. 5,616,142 to Yuan is respectfully traversed for the reasons noted above in connection with Borges. According to Yuan, his device is purely to stop extrusion of the bone graft from in between the vertebrae. It has no compressive function. The channels are purely

for alignment of the components rather than as a housing for a dynamic compression mechanism.

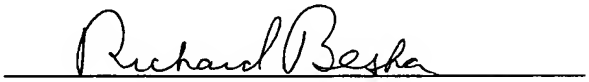
The rejection of claims 2-7 and 10 as unpatentable over Ralph in view of U.S. patent No. 3,659,595 to Haboush is respectfully traversed. Similarly, as Borges, Haboush cannot be used as a spinal fixation device in light of the longitudinally aligned screws and screw hole openings. There simply is not sufficient bone structure in the vertebrae to accommodate the arrangement of screws and openings as in Haboush. The device of Ralph as will be recalled does not postoperatively enable progressive advancement of the plates toward one another or enable the locking of the plates to one another in a plurality of advanced positions precluding movement in the opposite direction. A medical practitioner would not have considered it to have been obvious to add interlocking teeth to the Ralph device. The only purpose of the legs 102a and 102b, together with the screw thread, in Ralph is to permit the surgeon intraoperatively to adjust the length of the device. Providing interlocking teeth to Ralph would not serve that purpose since the length of the device would still remain adjustable and the plates would not be secured to one another in that selected adjustable length. That is, the teeth would still permit the plates to move relative to one another absent additional structure such as the set screw. This is contrary to the teaching of Ralph which requires the plates, once the length of the device is intraoperatively ascertained, to be secured to one another to maintain the selected length. Providing teeth to Ralph does not lock the plates in any position since the ratcheting action can still be maintained without some additional structure to lock the plates against relative movement. Consequently, to add interlocking teeth would not be consistent with nor advance the purpose of the Ralph device. Moreover, to add teeth to the Ralph device such that the two plates are locked intraoperatively to one another, (presumably by using the set screw) would preclude postoperative relative movement of the plates which, of course, is an objective of the present device as claimed. That is, even assuming the obviousness of applying ratchet teeth to the Ralph plates, the result is contrary to the presently claimed device.

The rejection of claim 9 based on Ralph and U.S. patent No. 5,549,612 to Yapp is respectfully traversed for the reasons noted above in connection with Ralph.

Accordingly, applicant believes that the application is now in condition for allowance and early notification of the allowance thereof is respectfully requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 
Richard G. Besha
Reg. No. 22,770

RGB:pfc
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100